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January 19, 2016

Eileen Fleck
Chief, Acute Care Policy and Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Ms. Fleck:

Thank you for the opportunity to participate on the Freestanding Medical Facility (FMF) workgroup and provide informal comment on the draft FMF regulations. We have made several informal comments which are summarized below and shown in red-lined version on the enclosed draft. Further, MIEMSS will be providing additional comments through the formal comment process which will address the role of MIEMSS and the EMS Board specific to FMFs. We look forward to discussions with you in this regard in due course.
MIEMSS informal comments on the draft regulation are as follows:

- MIEMSS believes the definition of "emergency services" on page 26 (5) should be used consistently throughout the document instead of "emergency *medical* services" which typically refers to prehospital care. To that end, we have deleted the word "medical" in several places in the draft.
- Secondly, we have added "reasonably be expected to" to the definition of "emergency medical condition" in order to be consistent with the EMTALA definition of "emergency medical condition".
- On page 27, in two places, we changed "emergency medical system" to "emergency medical service" which is the correct terminology at the jurisdictional level.
- In the definition of Freestanding Medical Facility, we have replaced item 7(g) on page 27 which provided that the FMF is "linked to MIEMSS" with the language that the FMF: "...WILL MAINTAIN ADEQUATE AND APPROPRIATE DELIVERY OF EMERGENCY CARE WITHIN THE STATEWIDE EMERGENCY MEDICAL SERVICES SYSTEM AS DETERMINED BY THE MARYLAND STATE EMERGENCY MEDICAL SERVICES BOARD." We believe this change is consistent with the intent and language previously discussed. We understand this wording may need to be more specific and look forward to working with MHCC to that end.

Our changes are shown in the "marked-up" version of the draft document enclosed.

Sincerely,

Kevin Seaman, MD

Cc: Ben Steffen
Executive Director, MHCC

the quality of services provided by hospitals' EDs.[28] It is also essential to evaluate care coordination for patients treated in hospital EDs and FMFs. According to the National Quality Forum (NQF), poor care coordination is associated with higher costs, increased medical errors, unnecessary patient suffering, and increased ED readmissions. NQF reported that care coordination initiatives could result in an estimated $240 billion in savings throughout the U.S.[29]

Rate Regulation

In Maryland, the Health Services Cost Review Commission regulates rates for hospital services by establishing global budgets for individual hospitals. It also establishes budgets for each freestanding medical facility. Due to expected volume shifts from a parent hospital to an approved freestanding medical facility, HSCRC will need to adjust the global budget of the parent hospital that is granted CON approval to establish a freestanding medical facility. Longer term, as volume potentially shifts, the global budgets of other hospitals may be affected.

Policy Objectives

The broad policy objectives guiding the Commission's regulation of freestanding medical facilities in Maryland serve as a foundation for the specific standards of this State Health Plan chapter and are as follows:

Policy 1: **Emergency ~~medical~~ services shall be financially and geographically accessible to Maryland's population.**

[28] Centers for Medicare and Medicaid. "Outcome Measures." https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/outcomemeasures.html.
[29] NQF-Endorsed Measures for Care Coordination: Phase 3, 2014.

Policy 2: **Emergency ~~medical~~ services shall be provided in the most cost-effective manner possible consistent with safely and effectively meeting the health care needs of patients needing emergency medical care.**

Policy 3: **Resources shall be used efficiently in producing emergency ~~medical~~ services. Development of excess emergency ~~medical~~ service capacity should be avoided. Resource capacity development shall match the acuity of patients' needs.**

Policy 4: **An FMF shall provide high quality care. Each FMF shall adopt performance measures and improve and adapt those measures over time, shall measure the FMF's level of achievement on the performance measures, and shall continuously seek to improve its level of achievement.**

Policy 5: **An acute care general hospital operating an FMF shall assess the primary care needs of the population in its service area and maximize the number of people in its service area who have a regular source of primary care. The hospital shall educate individuals and families in its service areas about appropriately using emergency medical facilities in order to reduce avoidable use of emergency services.**

Policy 6: **A hospital operating an FMF shall continuously and systematically improve the quality and safety of patient care. This includes planning, implementing, and optimizing the use of electronic health record systems and connecting to the State designated electronic health information exchange to reap the contribution to improved care coordination, patient safety, and quality improvement that adoption of these tools affords.**

.04 Standards

A. General Standards.

(1) An applicant for a Certificate of Need to establish, relocate, or expand a freestanding medical facility shall address and meet the applicable general standards in COMAR 10.24.10.04A in addition to the applicable standards in this chapter.

amount of time patients spent in the ED before being sent home; the percentage of patients leaving the ED without being seen; and the history of ambulance diversion at the parent hospital's ED.

b. If inadequate access and availability of emergency ~~medical~~ services form the basis of the applicant's justification to establish, relocate, or expand an FMF, the applicant shall demonstrate that access barriers exist based on studies or other validated sources of information and shall present a detailed, credible plan for addressing each barrier consistent with the proposed project;

(v) An explanation of how the proposed new, relocated, or expanded FMF will address each problem identified by the applicant;

(vi) A demonstration that the proposed project is consistent with the hospital's community health needs assessment;

(vii) A demonstration that the number of FMF treatment spaces and the size of the facility proposed by the applicant is consistent with the low end of the range indicated by reasonably projected levels of visit volume and other parameters, consistent with guidance provided in the most current edition of *Emergency Department Design: A Practical Guide to Planning for the Future,* published by the American College of Emergency Physicians; and

(viii) A demonstration that the applicant hospital, in cooperation with its medical staff and other public and private health care organizations in its community, has attempted to reduce use of its ED and, if applicable, its FMF for non-emergency medical care. This demonstration shall, at a minimum, address: the feasibility of reducing or redirecting individuals in the service area who have non-emergent

illnesses, injuries, and conditions, to lower cost alternative providers; and the actions taken by the hospital to accomplish those goals.

(2) Access.

An applicant shall address the following standards regarding access:

(a) A hospital shall demonstrate that its proposed FMF will improve access to emergency services for the population in the proposed service area of the FMF. This analysis shall include information on emergency transport times, return to service times, and other relevant information provided by each emergency medical ~~system~~ service for each jurisdiction to be served by the proposed FMF.

(b) The applicant shall identify problems with access to emergency ~~medical~~ services by underserved groups including low-income persons, uninsured persons, racial and ethnic minorities, and persons with disabilities residing in its existing or proposed service area, and shall develop a plan to overcome barriers to access for each underserved group identified; and

(c) A new or relocated FMF shall be located to optimize accessibility for patients who are currently served in the applicant hospital's service area. The applicant shall consult with each emergency medical ~~system~~service for each jurisdiction to be served by the proposed FMF in making this determination.

(3) Cost and Effectiveness.

An applicant proposing establishment, relocation, or expansion of an FMF shall demonstrate that the FMF project will cost-effectively achieve appropriate objectives. The applicant shall compare the costs and effectiveness of the proposed project with the costs and effectiveness of at least two alternative approaches for achieving project

(8) Quality Improvement

An FMF will provide high quality emergency ~~medical~~ services and continuously work to improve its quality of care. An applicant shall develop a systematic and comprehensive approach to evaluate quality of care utilizing CMS quality measures to evaluate healthcare processes and outcomes.

(a) The applicant shall describe an appropriate quality assurance program and performance measures that will be used by the proposed FMF and parent hospital or that are used by the existing FMF on an ongoing basis to monitor and improve the quality of care provided. At a minimum, an applicant shall provide information on the following time-based performance measures for the each hospital and existing FMF involved in the project:

(i) Median time from ED or FMF arrival to ED or FMF departure for patients admitted to the hospital or transferred from an FMF to a hospital for admission;

(ii) Median time from ED or FMF arrival to ED or FMF departure for discharged patients; and

(iii) Median time patients spent in the ED after a doctor decided to admit them before the patients were transferred to their inpatient rooms; and

(iv) Median time patients spent in an FMF prior to transfer to a hospital, after a doctor recommended admission; and

(v) Median time patients spend in the ED or FMF before they were seen by a healthcare professional; and

(vi) Percentage of patients who left the ED or FMF before being evaluated by a physician.

(3) "Community health needs assessment" means the assessment made at least once every three years by a hospital that qualifies as a nonprofit organization under Section 501(c)(3) of the Internal Revenue Code of 1954 and that is required by the Patient Protection and Affordable Care Act, 42 U.S.C. 18001, in which the hospital must define the community it serves and assess the health needs of that community.

(4) "Emergency medical condition" means a medical condition that manifests itself by acute symptoms of sufficient severity including severe pain, psychiatric disturbances, and symptoms of substance abuse such that the absence of immediate medical attention could reasonably be expected to result in:

(a) Placing the health of the individual in serious jeopardy;

(b) Placing the health of a pregnant woman or unborn child in serious jeopardy;

(c) Serious impairment to any bodily function;

(d) Serious dysfunction of any bodily organ or part; or

(e) With respect to a pregnant woman who is having contractions:

(i) Inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) The transfer posing a threat to the health or safety of the woman or the unborn child.

(5) "Emergency services" means health care services provided to evaluate and, as appropriate, treat emergency medical conditions.

(6) "EMTALA" means the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. §1395.

(7) "Freestanding medical facility" (FMF) means a health care facility that:

(a) Provides medical and health care services;

(b) Is an administrative part of an acute care general hospital;

(c) Is physically separated from the hospital or hospital grounds;

(d) Operates 24 hours a day, seven days a week;

(e) Complies with EMTALA and Medicare Conditions of Participation;

(f) Has the ability to rapidly transfer complex cases to an acute care general hospital after the patient has been stabilized; and

~~(g) Is linked to the Maryland Institute for Emergency Medical Services Systems (MIEMSS).~~ (g) WILL MAINTAIN ADEQUATE AND APPROPRIATE DELIVERY OF EMERGENCY CARE WITHIN THE STATEWIDE EMERGENCY MEDICAL SERVICES SYSTEM AS DETERMINED BY THE MARYLAND STATE EMERGENCY MEDICAL SERVICES BOARD.

(8) "Global budget revenue" or "global budgeting" means the methodology of the Health Services Cost Review Commission that:

(a) Is central to achieving the three-part aim set forth in Maryland's all-payer model of promoting better care, better health, and lower cost for all Maryland patients; and

(b) Focuses on controlling increases in total hospital revenue per capita; and encourages hospitals to focus on population-based health management by prospectively establishing a fixed annual revenue cap for each hospital that has a global budget revenue agreement with the Health Services Cost Review Commission.

(9) "Maryland State Health Improvement Process plan" means the most current plan developed by the Maryland Department of Health and Mental Hygiene and currently found at http://dhmh.maryland.gov/ship/SitePages/Home.aspx.